

## **II. REMARKS**

### **A. Status of the Claims**

Claims 1-6, 15-19, 22, 24-26 have been amended without prejudice or admission.

New claims 27-29 have been added.

Support for the new and amended claims can be found, e.g., in original claims 1 and 7-11, as well as in Examples 1-4 of the original specification. Amendments to claims 24-26 are supported, e.g., by paragraphs [0023]-[0025] of the original specification.

Applicants respectfully submit that no new matter has been added by virtue of the present amendments.

### **B. Claim Objections**

Claims 15-16, 18-21 and 23-26 have been objected to under 35 C.F.R. 1.75(c) "as being in improper form because a multiple dependent claim should refer to other claims in alternative only and cannot depend from any other multiple dependent claim." Office Action, page 2.

Applicants respectfully note that claims 15-16, 18-21 and 23-26 have been amended to remove multiple dependencies in the Preliminary Amendment filed on December 28, 2005.

Withdrawal of the objections is respectfully requested.

### **C. Claim Rejections- 35 U.S.C. § 101**

Claims 24-26 have been rejected under 35 U.S.C. § 101 because they "claimed recitation of a use, without setting forth any steps involved in the process." Office Action, page 2.

Claim 24 has been amended to recite:

A method of treating pain in a human patient comprising administering a dosage form of claim 1 to said patient.

Claims 25 and 26 have been amended to depend from claim 24.

Withdrawal of the rejection is respectfully requested.

**D. Claim Rejections- 35 U.S.C. § 112**

Claims 24-26 have been rejected under 35 U.S.C. § 112, second paragraph as “not supported by either an asserted utility or a well established utility.” Office Action, page 4.

Claims 24-26 have been amended as discussed above. It is respectfully submitted that the rejection has been rendered moot by the amendments to the claims. Accordingly, withdrawal of the rejection is respectfully requested.

**E. Claim Rejections- 35 U.S.C. § 103**

**1. U.S. 2003/0229111 to Oshlack et al.**

Claims 1-14, 17 and 22 have been rejected under 35 U.S.C. § 103(a) over U.S. 2003/0229111 to Oshlack et al.

The rejection is respectfully traversed.

Independent claims 1 and 22 have been amended without prejudice to recite that the ratio of naltrexone to hydrocodone in the claimed compositions is “from 0.011:1 to 0.0125:1.” The Oshlack patent does not describe the claimed ratio.

In response to the Examiner's statement on page 3 of the Office Action that "Table 20A [of Oshlack] exemplifies a composition comprising naltrexone hydrochloride in an amount of 0.5 mg and hydrocodone bitartrate in an amount of 5 mg, which meets the limitations of claim 1," Applicants respectfully note that the ratio of naltrexone to hydrocodone in Table 20 is "0.1:1" ( $0.5/5=0.1$ ), which is at least eight times higher than the ratio recited in claims 1 and 22.

In response to the Examiner's statement on page 3 of the Office Action that "Tables 22A, 23A, 24A, 25A, 26A and 27A [of Oshlack] exemplify a composition comprising naltrexone hydrochloride in an amount of 0.125 mg and hydrocodone amount of 5 mg," Applicants respectfully note that the ratio of naltrexone to hydrocodone based on these amounts is "0.025:1" ( $0.125/5=0.025$ ), which is at least double the ratio recited in claims 1 and 22.

The Oshlack patent does not therefore describe the claimed ratio, let alone suggest desirability of the ratio.

In the interest of compact prosecution, Applicants respectfully note that the Board of Patent Appeals and Interferences, in a precedential opinion *In Ex Parte Whallen II*, confirmed that:

... obviousness cannot be proven merely by showing that the elements of a claimed device were known in a prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed ... [Similarly,] obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that result in the claimed composition.

*In Ex Parte Whallen II, Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008.*

The Oshlack reference does not provide such a reason in the present case.

Withdrawal of the rejection is respectfully requested.

**2. U.S. 2003/0191147 to Sherman et al. in view of U.S. 2003/0031712 to Kaiko et al.**

Claims 1-14, 17 and 22 have been rejected over the combination of U.S. 2003/0191147 to Sherman et al. and U.S. 2003/0031712 to Kaiko et al. The Examiner stated that “Sherman et al. does not teach the exact amounts of naltrexone and hydrocodone as listed in claims 2-11 or that the compositions are interdispersed with a sustained release excipient” and has relied on the Kaiko reference to cure this deficiency. Office Action, page 5.

The rejection is traversed.

The combination of the cited references does not teach the specific naltrexone to oxycodone ratio recited in claims 1 and 22. Assuming *arguendo* that one skilled in the art was to consider the Sherman and the Kaiko references together, he or she would not envisage the ratio recited in claims 1 and 22.

The weight ratio naltrexone per 1 mg of hydrocodone recited in Tables 1 and 2 in the Kaiko reference is “0.033 to 0.267,” with a preferred ratio being “0.050 to 0.200.” This ratio is outside the ratio recited in present claims 1 and 22 (i.e., 0.011 to 0.0125), and is at least 2.6 times higher than the ratio recited in claims 1 and 22. The Sherman reference also does not describe the specific naltrexone to oxycodone ratio and the amounts recited in claims 1 and 22.

The combination of the cited references does not therefore provide a reason for one skilled in the art to combine hydrocodone with naltrexone in the ratio and in the amounts recited in claims 1 and 22, the ratio that is at least 2.6 times smaller than the ratio described in the Kaiko reference.

Withdrawal of the rejection is respectfully requested.

### **III. Conclusion**

An early and favorable action is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,  
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